DOCKET NO.: PUAM-0257 PATENT

Application No.: 10/631,883

Office Action Dated: October 6, 2006

REMARKS

Interview Summary

Applicants would like to thank Examiner Lundgren for extending them the courtesy of a telephonic interview on January 4, 2007. The participants of the interview were John W. Caldwell and Angela Verrecchio of Woodcock Washburn LLP, attorneys for Applicants; Laurie Tzodikov and Daniel Kahne, Applicants; and Examiner Jeffrey S. Lundgren.

The Applicants discussed the claims and responded to the Examiner's expressed view that the breadth issues were chiefly concerned with the specification of the core vancomycin structure rather than with the C6 substituents. Applicants agreed to propose an amendment in which the vancomycin core is more specifically limited to the native species with possibly limited modifications.

Claim Status

Claims 1, 5-11, 14-23, 26-32, 35-37, 102-107, 111, and 116 were pending in the present application. Claims 1, 102, 103, 105-107, and 116 have been amended, and claims 2-4, 7-25, 28-101, 104, and 108-115 canceled, without prejudice, for Applicants to pursue in a separate application. New claim 117 has been added. Support for claim 117 can be found through the Specification, at for example, pages 8-9, 16-17, and the examples. No new matter has been added. Claims 1, 5, 6, 26, 27, 102, 103, 105-107, 116, and 117 are therefore currently pending.

Claim rejections under 35 U.S.C. §112, first paragraph (enablement)

Claims 1, 5, 6, 11, 14, 15, 19-21, 23, 26, 27, 35-37, 102-107, 111, and 116 stand rejected under 35 U.S.C. §112, first paragraph for alleged lack of enablement. While Applicants disagree that the claims as written are not enabled, and that one skilled in the art would be able to make and use the invention, independent claims 1 and 102 have been amended to even more clearly define Applicants' invention. Claim 1 recites a "glycopeptide of the formula A₁-A₂-A₃-A₄-A₅-A₆-A₇, [SEQ ID NO:1] wherein the groups A₁ to A₇ comprise the heptapeptide structure of naturally occurring vancomycin..." which is modified at the C6 position of the vancomycin glucose, thereby providing even more clarity that the

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claimed invention encompasses vancomycin glycopeptides. Likewise, claim 102 has been amended to recite a vancomycin glycopeptide antibiotic with glucose C6 modifications. It is noted that the Examiner admits that the specification "provides guidance and examples directed to the making and use (e.g. antibiotic) of vancomycin glucose C6 substituted derivatives." Action at 5. Therefore, Applicants submit that the pending claims are sufficiently enabled and request withdrawal of the rejection.

Claim rejections under 35 U.S.C. §112, first paragraph (written description)

Claims 1, 5, 6, 11, 14, 15, 19-21, 23, 26, 27, 35-37, 102-107, 111, and 116 stand rejected under 35 U.S.C. §112, second paragraph for alleged lack of written description. While Applicants disagree that the claims as written do not convey to one of skill in the art that Applicants were in possession of the invention, claims 1 and 102 have been amended to even more clearly define the invention. Claim 1 recites a "glycopeptide of the formula A₁-A₂-A₃-A₄-A₅-A₆-A₇, [SEQ ID NO:1] wherein the groups A₁ to A₇ comprise the heptapeptide structure of naturally occurring vancomycin…" which is modified at the C6 position of the vancomycin glucose, thereby providing even more clarity that the claimed invention encompasses vancomycin glycopeptides. Likewise, claim 102 has been amended to recite a vancomycin glycopeptide antibiotic with glucose C6 modifications. These amendments provide greater clarity that the claimed invention encompasses modified vancomycin glycopeptides, which is adequately described throughout the specification, including as evident by the Table of synthesized compounds appearing at pages 131-135.

Applicants submit that it would be apparent to one of ordinary skill in the art that Applicants were in possession of the claimed invention at the time of filing, thereby fulfilling the requirements of the first paragraph of 35 U.S.C. §112. Withdrawal of the written description rejections is requested.

Claim rejections under 35 U.S.C. §102(b)

The Action contends that claims 1, 5, 6, 11, 14, 15, 19-21, 23, 26, 27, 35-37, 102-107, 111, and 116 are anticipated by Higgins, et al., U.S. Patent No. 4,548,925 (hereinafter "the Higgins reference"). According to the Examiner, the Higgins reference anticipates the

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present invention because it teaches a vancomycin derivative, wherein the derivative has an amino-modified sugar. Applicants respectfully disagree.

For a rejection under 35 U.S.C. §102(b) to be properly founded, the cited reference must teach, either expressly or inherently, each and every element of the claimed invention. *See, e.g., Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 U.S.P.Q. 81 (Fed. Cir. 1986).

The Higgins reference fails to teach each and every element of claims 1 and 102 (and consequentially the dependent claims). Claim 1 claims glycopeptides wherein, *inter alia*, "the group A₄ is linked via a glycosidic bond to a disaccharide having a glucose residue directly attached to said A₄ residue, wherein *said glucose residue bears an N-substituted aminohexose residue and at least one substituent of the formula YXR*" (emphasis added). The Higgins reference fails to teach a glucose residue bearing both an N-substituted aminohexose residue and at least one substituent of the formula XYR, as defined by Applicants'. For at least this reason, the Higgins reference can not be said to anticipate claim 1.

Likewise, claim 102 claims a glycopeptide antibiotic bearing at least one disaccharide group containing two saccharide groups "a first of said saccharide groups bearing at least one amino group, and a second of said saccharide groups linked directly to said glycopeptide bears at least one substituent of the formula XYR." Again, the Higgins reference fails to teach at least one substituent of the formula XYR attached to the saccharide group attached directly to the glycopeptide. For at least this reason, the Higgins reference can not be said to anticipate claim 102.

Since the Higgins reference fails to teach each and every element of independent claims 1 and 102, it follows that it also fails to teach each and every element of the dependent claims. Withdrawal of the rejection over the Higgins reference is requested.

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Conclusion

Applicants submit that claims 1, 5, 6, 26, 27, 102, 103, 105-107, 116, and 117 are in condition for allowance. An early Notice of Allowance is respectfully requested. If the Examiner disagrees, he is invited to telephone the undersigned.

Date: January 10, 2007

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